

## **REMARKS**

Claims 1-21, 23-28, and 31 remain in the present application. Claims 1, 9, 17, 20, 23, 27, and 31 are the only claims in independent form.

This preliminary amendment is being filed in response to an Office Action dated October 6, 2003, Paper Number 5, issued during the prosecution of the parent application (U.S. Serial No. 10/124,945). Specifically referring to the Office Action, claim 26 has been rejected under 35 U.S.C. § 112, second paragraph, for being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. More specifically, the Examiner holds that the limitation "said set screw" does not have sufficient antecedent basis in the claim. In response thereto, claim 26 has been amended to specifically depend upon claim 24 instead of claim 23. As a result, proper antecedent basis exists and reconsideration of the rejection is respectfully requested.

Claims 1-6, 9-15, 17-21, 23, 27, and 31 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,443,467 to Biedermann, et al. (hereinafter, "the '467 patent"). According to the Examiner, the '467 patent discloses a screw and rod fixation device that includes fixing means having an inner surface wall with a gripping portion and a non-gripping portion. The Office Action interprets the spherical seat of the receiver member as having an inner surface wall with a gripping portion and non-gripping portion. However, the portion identified as 9 in the figures is actually a small coaxial section and is not at all a gripping portion. As set forth in the specification of the '467 patent at column 2, lines 50-55, the small coaxial section 9 is immediately adjacent to the first bore and has a spherical surface towards the open end, whereby the radius of the spherical surface corresponds substantially to the radius of the spherical segment-shaped portion of the screw head 3. Moreover, the second bore has an internal thread 10, which extends coaxially from the section 9 to the free end. This section of the device is merely a spherical seat in the body whereby the bone screw merely sits or is situated within. The receiver member, as described in

the specification of the '467 patent, does not grip or lock the bone screw in place because the first bore within the receiver member has a radius that corresponds substantially to the radius of the spherical segment-shaped portion of the screw head (see, column 2, lines 50-55). Therefore, there is no mechanism that can engage the side wall of the bone screw. This does not create an inner wall with a gripping surface as set forth in the outstanding Office Action. This portion of the receiver member merely creates a stop mechanism that the bone screw can be pressed or forced against.

In contradistinction, the presently claimed invention does not merely claim a spherical seat in which the bone screw head will be stopped or is situated within. It also claims a gripping portion whereby the screw head engages the side wall of the rod seating mechanism and does not allow for the screw head to be released. Therefore, once the screw is set in place within the rod receiving mechanism of the present invention, the screw head forces expansion of the inner surface wall of the fixing mechanism and is therefore locked in place. On the other hand, the '467 patent requires an additional screw to lock the bone screw in place. As a result, if any of the components situated above the bone screw are removed (e.g., the rod locking nut 13 or a lock nut 14), the bone screw would be loosened from the body.

In addition to the above differences, the '467 patent discloses the use of an inner set screw and an outer nut to avoid spreading of the receiving member body. As set forth in column 2, lines 7-12, the '467 patent teaches a design that has an inner set screw and a nut. Since spreading of the body is a significant problem, the '467 patent requires the use of the inner set screw and outer nut to prevent spreading therein. In contradistinction, the presently claimed invention does not claim an external set screw to prevent the spreading of the claimed assembly. Due to the above differences, the presently claimed invention is not anticipated by the '467 patent. Reconsideration of the rejection is respectfully requested.

Claims 7-8, 16, 24-26, and 28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the '467 patent in view of U.S. Patent No. 6,280,442 to Barker, et al. (hereinafter, "the '442 patent"). According to the Examiner, the '467 patent discloses the claimed invention except for the locking mechanism defined as a set screw and fixing means made of a semi-flexible material and an annular ring having a gap portion. First, as set forth above, the '467 patent is clearly different from the presently claimed invention. More specifically, the locking mechanism of the presently claimed invention is not at all disclosed in either the '467 patent or the '442 patent. As described above, the locking mechanism of the presently claimed invention includes a gripping portion whereby a bone screw can be locked within the presently claimed device. In other words, no additional components are required to lock the bone screw within the presently claimed device. This is different from the device disclosed in the '467 patent.

As for the '442 patent, a multi-axial bone screw assembly is disclosed whereby the screw head of the bone screw does not at all engage the side wall of the body of the assembly. The screw is locked into place within the assembly through engagement of small projections from the head of the screw and compressing an insert against these projections. (See, Figures 2, 4, and 7). In contradistinction, the presently claimed invention is directed towards a locking mechanism that allows expansion of the side walls and engagement thereto with the bone screw, which provides enhanced screw head locking. The manner in which the screw head is locked into place is through a gripping portion of the inner surface wall of the fixing mechanism that expands as the screw head is inserted into the fixing mechanism. (See, Figures 1A and B of the present application that illustrate the manner in which the screw head 14 is locked into place as it is inserted into the fixing mechanism). As a result of the differences set forth above, the presently claimed invention is not only novel in view of the cited prior art references, but also unobvious. As a result, reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above. The prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

In summary, the presently claimed invention is patentably distinct over the prior art. As a result, the presently claimed invention is now in condition for allowance, which allowance is respectfully requested.

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Respectfully submitted,

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